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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/775,442	02/10/2004	Jamie S. Henderson	760-75 DIV	9424

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EXAMINER

PREBILIC, PAUL B

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 07/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No. 10/775,442	Applicant(s) HENDERSON, JAMIE S.	
	Examiner Paul B. Prebilic	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 February 2004.
 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) ☐ Claim(s) _____ is/are allowed.
 6) ☒ Claim(s) 1-8 is/are rejected.
 7) ☐ Claim(s) _____ is/are objected to.
 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
 10) ☒ The drawing(s) filed on 10 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>2/10/04</u> . | 6) <input type="checkbox"/> Other: _____ |

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 1, the language "twisting said second tube into a helical configuration" is not clear based upon the manner in which the invention is disclosed because a helical tube in a helical shape is not formed by the method disclosed. Rather, fibrils of the ePTFE structure become helically oriented as the tube graft is twisted with respect to the longitudinal axis. For this reason, it is not clear how to interpret the language because it is unclear with respect to the invention as disclosed. Claim 6 has the same vague language and claims 2-5, 7, and 8 are vague because they depend upon claim 1.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 6-8 are rejected under 35 U.S.C. 102(b) as being anticipated by D'Onofrio (US 3,730,229). D'Onofrio anticipates the claimed method where the preamble is treated as a statement of intended use as not being required for the body of the claim, and the tubes of D'Onofrio can be made of stainless steel such that this

material is biologically compatible in a living organism; see the figures and column 5, line 57 et seq.

With regard to claim 6, the claim language is read upon by D'Onofrio because opposite ends of each tube are twisted in opposite directions such that one end of one tube is oppositely twisted from the other end of another tube.

With regard to claims 7 and 8, tubes can be placed over or between the other tubes and since they are metal they are radially expandable by at least twisting or pressurizing them. And the other tubes are support members because they are metal members that hold their shape.

Claims 1, 5, 7, and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Vittorio et al (GB 2204945). Vittorio anticipates the claim language where the tubes are bonded to each other by gaskets; see the abstract and page 22, line 22 to page 3, line 27.

Claims 1, 7, and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Leone et al (US 5,891,108). Leone anticipates the claim language where the first tube is catheter (16) or sheath (30), the second tube as claimed is the tubular wire stent (12) that is inherently twisted into the helical shape by a mandrel and then fixed to the balloon and sheath prior to delivery; see Figures 1 to 4 and column 2, line 50 to column 4, line 23.

Regarding claims 7 and 8, the support member is the sheath (30) or the catheter (16).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-8 are rejected under 35 U.S.C. 102(b) as anticipated by Brauker et al (WO 00/43052) or, in the alternative, under 35 U.S.C. 103(a) as obvious over Brauker et al (WO 00/43052) alone. Brauker anticipates the claim language where the first tube or second tube can be helical with a longitudinal seam (see Figure 5B) indicating that the helical form of the fibrils is formed as the sheet is twisted into a tubular form. Due to the vagueness of the present claim language it is unclear how to interpret the language "twisting said second tube into a helical configuration" so it has been given a broad interpretation; see Figures 2A, 5B and 8C, page 12, line 3 to page 13, line 15, page 14, line 28 to page 15, line 17 and page 18, lines 6-34..

Alternatively, one could view the claim language as not being met by Brauker because it is not clear that twisting the second tube into a helical configuration is literally met. However, the Examiner asserts that it reasonably appears that a step similar to that claimed is disclosed by Brauker such that the claimed method would have been considered prima facie obvious to an ordinary artisan.

Conclusion

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be

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applicable under 35 USC 102 of 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action if the application is not stored in image format (i.e. the IFW system) or published.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Paul B. Prebilic whose telephone number is (571) 272-4758. He can normally be reached on 6:30-5:00 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, McDermott Corrine can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Paul Prebilic
Primary Examiner
Art Unit 3738